

## **Exhibit D**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,996	11/15/2001	Peter M. Bonatti	BON-1360-8	8298

7590 12/30/2002

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EXAMINER
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BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/003,996 Examiner Jessica R Baxter	Applicant(s) BONUTTI, PETER M. Art Unit 3731
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> <li>- If no period for reply is specified above, the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If the period for reply is specified above, the shorter of the period specified or thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any gained patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
<p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>15 November 2001</u>.</p> <p>2a)<input type="checkbox"/> This action is FINAL.                  2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<b>Disposition of Claims</b>		
<p>4)<input checked="" type="checkbox"/> Claim(s) <u>1 and 36-76</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1,36-40,42-55,57-70,73 and 74</u> is/are rejected.</p> <p>7)<input checked="" type="checkbox"/> Claim(s) <u>41,56,71,72,75 and 76</u> is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b>		
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.            Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.            If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
<p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:            1.<input type="checkbox"/> Certified copies of the priority documents have been received.            2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.            3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b>		
<p>1)<input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.            5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            6)<input type="checkbox"/> Other:</p>		

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 36, 37, 38, 39, 40, 48 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 19, 20, and 21 of U.S. Patent No. 5,403,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a surgical procedure comprising removing tissue from a first location in the patient's body under the influence of suction and by rotating a cutting tool, separating one or more components from at least a portion of the tissue removed by centrifugation, packing the tissue, adding a substance to the tissue after separating one or more components from the tissue, and implanting the tissue at a second location.

3. Claims 36, 37, 39, 40 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,694,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a surgical procedure comprising removing tissue from a first location in the patient's body under the influence of suction and by rotating a cutting tool, separating one or

more components from at least a portion of the tissue removed by centrifugation, packing the tissue, and implanting the tissue at a second location.

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,269,785. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a tissue removal apparatus comprising a flexible drill member, a cutting tip mounted on said shaft, means for transmitting motion to said shaft, and means for removing tissue fragments along said shaft by suction.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,857,045 to Rydell. A tissue removal apparatus comprising a flexible drill member (12), a cutting tip mounted on said shaft (32), means for transmitting motion to said shaft (Column 6 lines 5-23), and means for removing tissue fragments along said shaft by suction (FIG. SUCTION at 64).

7. Claims 36-39, 42-47, 49-55, 57-59, 69, 70, 73 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,226,877 to Epstein.

Regarding claim 36, 37, 42 and 44, Epstein discloses a surgical procedure comprising the steps of removing tissue comprised of blood from a first location (Column 6 lines 1-4), separating one or more components from at least a portion of the tissue by centrifugation (Column 7 lines 13-23), and implanting the tissue at a second location (Column 10 lines 45-60).

Regarding claim 38, 53 and 73, Epstein discloses that a further step of adding a substance to the body tissue (Column 6 lines 37-61) after separating one or more substances from the tissue and prior to implanting the body tissue at a second location in the patient's body.

Regarding claim 39, 54 and 74, Epstein discloses that the step of cutting the body tissue at the first location and moving the body tissue away from the first location under the influence of suction (Column 7 lines 13-23).

Regarding claim 43 and 45, Epstein discloses that the step of removing tissue includes removing blood and other tissue, said step of separating one or more components includes separating a component from the blood and then implanting the other tissue and blood at a second location (Column 1 lines 37-45 and Column 10 lines 53-60).

Regarding claims 46 and 58, Epstein discloses that said step of separating one or more components from the body tissue includes filtering the tissue (see Column 6 lines 1-61).

Regarding claims 47 and 59, Epstein discloses the step of moving the removed tissue into a trap before implanting (Column 7 lines 31-52).

Regarding claims 49, 50, 57 and 69, Epstein discloses the use of a first tubular member to remove tissue from a first location (Column 7 lines 13-23) and said step of implanting tissue includes inserting a second tubular member into the patient's body and moving tissue through the second tubular member (Column 10 lines 53-60).

Regarding claim 51, Epstein discloses the step of separating one or more components prior to moving the tissue through the second tubular member (Column 7 lines 13-23).

Regarding claim 52, Epstein discloses that centrifuging is used to separate a component from the tissue (Column 7 lines 13-23).

Regarding claim 55, Epstein discloses that includes the step of cutting body tissue with a cutting tool which is driven under the influence of force (Column 7 lines 13-23).

Regarding claim 70, Epstein discloses that the step of separating one or more components includes centrifuging (Column 6 lines 1-61).

#### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 61-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,678,470 to Nashef et al. in view of Epstein '877.

Nashef discloses removing other body tissue (Column 3 lines 22-34), shaping the body tissue (Column 2 lines 39-47), and implanting the body tissue (Column 2 lines 52-59). Nashef does not disclose the removal of blood. Epstein teaches that blood may be removed to form an adhesive for use in tissue grafting, specifically bone (Column 5 lines 11-14), that is biocompatible and can be prepared at the time of operation (Column 1 lines 38-42). Nashef discloses that his bone grafting material must be secured to the body by any conventional methods known in the art (Column 5

lines 28-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the blood derived adhesive of Epstein to adhere the bone grafting material of Nashef into the implantation site.

*Allowable Subject Matter*

10. Claims 41, 56, 71, 72, 75 and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to tissue cutting and removal devices:

- U.S. Patent No. 5,027,827 to Cody et al.
- U.S. Patent No. 6,261,295 to Nicholson et al.
- U.S. Patent No. 6,325,806 to Fox
- U.S. Patent No. 6,358,252 to Shapira
- U.S. Patent No. 6,409,764 to White et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

jrb  
December 16, 2002

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700